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10/517,666	12/13/2004	Michal Eisenbach-Schwartz	EIS-Schwartz37	7353

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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/517,666	EISENBACH-SCHWARTZ ET AL.	
	Examiner	Art Unit	
	Daniel Kolker	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The remarks and amendments filed 29 October 2007 have been entered. Claims 1 – 22 and 38 – 39 have been canceled; claims 23 – 37 are pending and under examination.

Withdrawn Rejections and Objections

2. The following rejections and objections set forth in the previous office action are withdrawn:

A. The objections are withdrawn in light of the amendments which cancel non-elected subject matter and correct grammatical mistakes.

B. The rejection under 35 USC 102(b) over Huang (2000. Clin Exp Immunol 122:437-444) is withdrawn in light of the amendments. The independent claims now require that the cells be administered to patients suffering from diseases. Huang teaches administration of cells as recited in the claims to patients who do not yet have disease, i.e. as a treatment to induce tolerance to a later induction of EAE. Thus the reference in not within the scope of the claims as currently written.

Maintained Rejections

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23 – 37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for administration of dendritic cells pulsed with residues 87 – 99 of myelin basic protein or the same peptide wherein the lysine at residue 91 was replaced with alanine and subsequent attenuation of locomotor symptoms in patients with spinal cord injury, does not reasonably provide enablement for:

- administration of cells pulsed with any and all NS-specific antigen or analog or derivative thereof as broadly claimed in independent claims 23, 31, and 36, or for
- treatment of all diseases or conditions as recited in claim 31
- treatment of the specific diseases and conditions recited in claims 32 – 33.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

This rejection is maintained for the reasons made of record in the office action mailed 27 April 2007. Briefly, the claims encompass inhibiting neuronal degeneration by administering cells that have been pulsed with a nervous system (NS)-specifc antigen or analog, or a peptide derived from said antigen, or an analog or derivative of the peptide. The specification discloses, beginning at p. 23, the results of experiments in which rats that received dendritic cells (DCs, which are a type of antigen-presenting cells) that had been pulsed with either a) a peptide consisting of residues 87 – 99 of myelin basic protein (called MBP 87 – 99) or b) or the same peptide wherein the lysine at residue 91 was replaced with alanine (called A91) monitored for recovery from spinal cord injury. However the specification does not reasonably provide enablement for the full scope of NS-specific antigens and analogs as broadly defined, and does not reasonably provide enablement for treating diseases as broadly claimed. The reasons why the claims are not enabled over their full scope is set forth in detail in the previous office action and for the sake of brevity will not be reiterated here.

Applicant argues, on pp. 9 – 12 of the remarks filed 29 October 2007, that the claims are enabled over their full scope. Specifically, applicant argues that the "invention is not directed to the treatment of autoimmune diseases. It is directed to treatment of secondary degeneration that follows a primary injury in the CNS or PNS". While this may be applicant's interpretation of the claims, the examiner notes that no claim is limited to treatment of secondary neuronal degeneration that follows primary injury. Independent claim 23 only requires that the individual be suffering from any "injury, disorder or disease of the CNS or PNS" and that the appropriate pulsed cells be administered. Independent claim 31 similarly encompasses treating "an injury, disorder or disease of the CNS or PNS" by administering the cells. The independent claims both clearly encompass any patient with any CNS or PNS disease, such as multiple sclerosis. Thus the findings of Huang (2000, of record), which indicate that many embodiments within the scope of the claims will not work, are certainly on point to the instant claims.

Additionally, at p. 10 of the remarks applicant argues that "in the present invention the damaged to the nervous system is induced by injury to the spinal cord which exposes the immune system to all nervous specific antigens, including MOG and PLP, that therefore would have the same potential beneficial effect as the MBP peptide." Again, applicant is reminded that

the scope of the claims is considerably broader than ameliorating spinal cord injury, and encompasses inhibiting neuronal degeneration in any patient with any injury, disorder, or disease of the CNS or PNS (claim 23), or treating any such disease (claim 31), including epilepsia, glaucoma, drug addiction, and even vitamin deficiency (claim 33). The claims are clearly not limited to ameliorating spinal cord injury; while that aspect of the invention might be considered to be enabled, the full scope of the claims are not enabled and could not be enabled in the absence of undue experimentation.

In support of the argument that the claims are enabled for treating all diseases of the CNS and PNS, applicant points to the articles by Schwartz, Friedlander, and Vajda submitted with the response. The articles have been thoroughly reviewed but they do not support enablement for the full scope of the claims in the absence of undue experimentation. For example, the article by Schwartz discusses in detail the role of protective autoimmunity in ameliorating experimental autoimmune encephalomyelitis (EAE; an art-accepted model of human multiple sclerosis) by administering T-cells reactive to MBP (see for example p. 408). The article also mentions in passing that T-cells reactive to Cop-1, a random copolymer which is not a nervous system specific antigen or analog or derivative thereof and therefore not within the scope of the instant claims, were neuroprotective in models of some diseases (p. 410 second column second paragraph). However the article does not provide sufficient guidance as to which NS-specific antigens should be used for treatment of which diseases, and does not reasonably provide enablement for the full scope of treating diseases generically as encompassed by claim 31 or for the all the diseases listed in claim 33, such as vitamin deficiency, amnesia, or diabetic neuropathy. The references by Friedlander and by Vajda show that some of the diseases recited in claim 33 have certain mechanistic features in common, including cell death, but do not provide enablement for the inventions now claimed.

For the reasons above and those explained in further detail in the office action mailed 27 April 2007, the skilled artisan would have to resort to undue experimentation in order to practice the full scope of the claimed methods. Thus the rejection stands.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 23 – 28, 31 – 34, and 36 stand rejected under 35 U.S.C. 102(b) as being anticipated by Eisenbach-Schwartz (U.S. Patent 5,800,812, of record).

This rejection is maintained for the reasons made of record in the office action mailed 27 April 2007 and explained in further detail below. Briefly, Eisenbach-Schwartz teaches contacting dendritic cells with nerve segments and administering the cells to patients in need of treatment, including humans with spinal cord injury. The reasons why each claim limitation is met are set forth in the previous office action and for the sake of brevity will not be repeated here.

Applicant argues, on pp. 12 – 13 of the remarks, that the nerve segments used by Eisenbach-Schwartz do not reasonably constitute a NS-specific antigen and therefore the reference is outside the scope of the claims. Applicant cites a dictionary definition and Wikipedia entry which indicate that a antigen can be a single molecule, not a tissue. According to applicant, the nerve segments used by Eisenbach-Schwartz do not constitute an antigen.

Applicant's arguments have been fully considered but they are not persuasive. The examiner agrees that the definitions of "antigen" set forth by applicant are in fact reasonable. However, the nerve segments used by Eisenbach-Schwartz in fact contain many such NS-specific antigens. As they are segments, they would reasonably be severed at both ends, and thus NS-specific molecules, for example neurofilaments and neurotransmitters, would be leaking out of the severed nerve segments. Additionally, the segments would be expected to have NS-specific antigens on their surface, including but not limited to myelin, which coats nerves, sodium channels, which are present at the nodes of Ranvier, and neurotransmitter receptors, which are present on the surface of nerves. The claims as written do not require that any one particular NS-specific antigen be present, and do not require that the antigen be

isolated away from other NS-specific antigens. As the reference by Eisenbach-Schwartz clearly sets forth all the steps recited in the claims, the rejection stands.

5. Claims 23 – 28, 31 – 34, and 36 stand rejected under 35 U.S.C. 102(a) and under 35 USC 102(e) as being anticipated by Eisenbach-Schwartz (U.S. Patent 6,267,955, of record). Note the reference qualifies as prior art under both § 102(a) and § 102(e).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Note that even if applicant is able to overcome the rejection under 102(e) as described in the previous paragraph, the reference still qualifies as prior art under 102(a) as it in by another and was published before the earliest effective filing date of this application.

This rejection stands for the reasons of record. The disclosure of the '955 patent is similar to that of the '812 patent, which is the subject of the preceding rejection. Applicant argues that "a nerve segment is not an antigen as is required by the present claims." As described in further detail above, the nerve segments have a plethora of NS-specific antigens, there is no requirement in the claims for selection of any one particular antigen, and there is no requirement in the claims that the antigen be isolated from other antigens. Thus the rejection stands for the same reasons the previous rejection stands.

6. Claims 23, 28, 31, and 35 stand rejected under 35 U.S.C. 102(b) as being anticipated by Ben-Nun et al. (1990. European Journal of Immunology 20:357 – 361).

Ben-Nun teaches pulsing antigen-presenting cells, specifically macrophages, with MBP and subsequent administration to mice that had already had EAE induced. See p. 357 – 358 (sections 2.1 – 2.2) for a description of the procedure. Ben-Nun teaches that the procedure is sufficient to attenuate the development of EAE (see paragraph spanning pp. 358 – 359). Thus as the reference teaches administration of the antigen-presenting cells that had been pulsed with MBP, a NS-specific antigen, and subsequent attenuation of severity of symptoms of EAE, it fairly anticipates independent claims 23 and 31. Claim 28 is rejected as Ben-Nun teaches

culturing the antigen-presenting cells in the presence of IFN-gamma (see p. 358 first complete paragraph). Claim 35 is rejected as the reference teaches intraperitoneal administration is sufficient to treat the disease.

Applicant argues that as the claims now require either systemic administration or administration locally at the site of injury or disease, the prior art reference by Ben-Nun is beyond the scope of the claims. Specifically, applicant argues that since Ben-Nun teaches that i.v. administration is without effect, the i.p. administration which in fact was effective should not be considered systemic administration. According to applicant, this indicates that the therapy in Ben-Nun operates by a different mechanism than that thought to underlie the instant disclosure.

Applicant's arguments have been fully considered but they are not persuasive. The examiner is unable to determine why i.p. administration is successful and i.v. administration is not. Nonetheless, i.p. administration can reasonably be considered to be systemic administration. See for example Acton (U.S. Patent 5,719,296, issued 17 February 1998, specifically column 13 lines 4 – 35), and Falb (U.S. Patent 5,807,708, issued 15 September 1998, specifically column 35 lines 10 – 12), each of which defines intraperitoneal (i.p.) administration to be a form of systemic administration. As the reference by Ben-Nun teaches all of the claimed starting materials and steps, including i.p. administration which clearly is systemic, it anticipates the claims.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 23, 28, 31 – 32, and 34 – 36 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Ben-Nun et al., in view of Hauben (of record), Popovich (of record), and Schwartz (of record).

This rejection stands for the reasons previously made of record. The reasons why each claim limitation is met are set forth in the previous office action and for the sake of brevity will not be repeated here. Briefly, Ben-Nun teaches treatment of a disease, specifically EAE, by

administration of antigen-presenting cells (which present their antigen to T cells) that have been pulsed with the NS-specific antigen MBP; Hauben teaches treatment of spinal cord injury by administration of T cells that recognize the NS-specific antigen MBP. Popovich teaches the similar natures and mechanisms of EAE and spinal cord injury, providing motivation to the artisan of ordinary skill to use the therapies known to be effective for one of these conditions in methods of treating the other. Finally, Schwartz teaches that the presence of T cells reactive against NS-specific antigens in the central nervous system is not a sign of illness or infection, but rather a therapeutic mechanism by which the immune system attenuates disease, providing the motivation to the artisan of ordinary skill to increase the activity of the immune system within the CNS.

It would have been obvious to one of ordinary skill in the art to administer antigen-presenting cells that have been pulsed with MBP, as taught by Ben-Nun, for treatment of spinal cord injury. The motivation to do so would be to treat patients with spinal cord injury. It would be reasonable to expect success; such expectation comes directly from the prior art references themselves. While the reference by Hauben teaches administration of T cells rather than antigen-presenting cells, since antigen-presenting cells in fact present their antigens to T cells, it would have been obvious to substitute the APCs for the T cells. The motivation to make such a substitution is provided by Schwartz, who teaches that the CNS is immunologically privileged, so it would need APCs to be administered locally. Popovich further provides a reasonable expectation of success as the reference teaches the symptoms and mechanisms underlying EAE and spinal cord injury are similar, thereby providing the expectation that treatments for the former (i.e. as taught by Ben-Nun) will be successful in patients with spinal cord injury.

Applicant argues, on pp. 16 - 17 of the remarks, that there is insufficient motivation to combine the teachings of the various references, as they rely on different mechanisms of action to have their effect. The examiner disagrees; as set forth in the rejection under 35 USC 102(b) above, the reference by Ben-Nun clearly teaches that systemic administration of cells pulsed with MBP is therapeutically effective. Additionally, the reference by Popovich teaches many of the similarities between EAE and spinal cord injury, providing the motivation to use treatments known to be effective for the former in patients suffering from the latter. Thus the rejection stands.

8. Claims 23, 28, 31 – 32, and 34 – 37 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Ben-Nun in view of Hauben, Popovich, and Scwartz as applied to claims 23, 28, 31 – 32, and 34 – 36 above, and further in view of Gaur (1997. Journal of Neuroimmunology 74:149 – 158).

This rejection stands for the reasons of record. The reasons why claims 23, 28, 31 – 32, and 34 – 36 are obvious are set forth in the previous rejection. However none of the cited references teach the protein of SEQ ID NO:4 as recited in claim 37.

Gaur teaches the protein of SEQ ID NO:4. It is referred to as "A91" and is residues 87 – 99 of MBP, with a K to A substitution at residue 91 (see p. 150 section 2.2). The peptide, when administered to animals with EAE, ameliorates the symptoms of the disease (p. 152, section 3.2). Furthermore, the peptide stimulates cytokine production by the MBP-reactive T-cells (see for example Figure 5 and section 3.4). However Gaur does not teach administration of antigen-presenting cells that have been pulsed with this peptide.

It would have been obvious to one of ordinary skill in the art to pulse the antigen presenting cells with the protein of SEQ ID NO:4 (i.e. A91, taught by Gaur) prior to administration for treatment of spinal cord injury. The motivation to do so would be to effectively treat spinal cord injury. Applicant did not separately traverse this rejection but argued that the teaching of Gaur do not correct the deficiencies of the other references. As set forth above, there is no deficiency of the references, so the rejection stands.

Rejections Necessitated by Amendment

Claim Rejections - 35 USC § 103

9. Claims 23 – 34 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eisenbach-Schwartz (U.S. Patent 5,800,812, of record) in view of Huang (2000, of record).

The reasons why claims 23 – 28, 31 – 34, and 36 are anticipated by Eisenbach-Schwartz are set forth in the rejection under 35 USC 102(b) above. While the patent teaches culturing antigen-presenting cells in the presence of NS-specific antigens and subsequent treatment of injuries/diseases of the nervous system, Eisenbach-Schwartz does not explicitly teach culturing the cells in a medium comprising IL-4, GM-CSF, or both as recited in claim 29.

Huang teaches pulsing dendritic cells, which are antigen presenting cells, with myelin basic protein peptide 68 – 86, which is a peptide derived from a NS-specific antigen as recited in claim 23. Huang teaches administration of the dendritic cells to patients (rats), induces protection against subsequent induction of EAE, which is a degenerative disease. Huang teaches that the dendritic cells are cultured in medium comprising both IL-4 and GM-CSF (see p. 438 second paragraph), which is on point to claims 29 and 30. However Huang does not explicitly teach treating patients suffering from disease, as the reference is on point to prevention rather than treatment.

It would have been obvious to one of ordinary skill in the art to use the medium comprising both IL-4 and GM-CSF taught by Huang in the culturing step of Eisenbach-Schwartz. The motivation to do so would be to select a culture medium suitable for survival of antigen-presenting cells. Both Eisenbach-Schwartz and Huang teach culturing APCs, and it is prima facie obvious to substitute one medium for the other when both are known to be effective for the same purpose (here, growing antigen-presenting cells pulsed with NS-specific antigens *in vitro*); see MPEP § 2144.06(II).

10. Claims 23 – 29, 31 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huang (2000. Clin Exp Immunol 122:437-444, reference AE on IDS filed 18 August 2005) in view of Link (2001. Journal of Neuroimmunology 114:1-7).

Huang teaches inducing tolerance in patients who do not yet have the disease, by administration of APCs that have been pulsed with NS-specific antigen MBP 68-86, which is on point to claims 23 and 31, drawn to administration of the cells, as well as claims 25 (dendritic cells) and 28 (GM-CSF-containing medium, see p. 438 second paragraph). The rats are administered the cells subcutaneously, which is on point to claim 35. However the reference does not explicitly teach treating those patients after the CNS disease has been induced, and does not explicitly teach administration of human dendritic cells, autologous to the patient in need, obtained from skin, spleen, thymus, marrow, lymph nodes, or peripheral blood as encompassed by claims 24 – 27.

Link teaches administration of autologous dendritic cells that have been "exposed to a selected biological milieu in vitro" and then returning the cells to the same patient (see section 4,

beginning at the bottom of p. 3). This is autologous treatment and is on point to claim 26. Link teaches that this sort of therapy will be useful for treatment of human autoimmune diseases such as multiple sclerosis, which is the human correlate of EAE. While claim 27 recites product-by-process limitations as to where the dendritic cells may be obtained, it is noted that Link teaches dendritic cells from spleen are sufficient (p. 4, first complete paragraph). Thus Link teaches administration of autologous dendritic cells to patients in need, where the cells are obtained from spleen, and therefore is on point to the limitations of claims 24 – 27. Link also teaches that when inducing tolerance to EAE, one can treat the APCs from patients who already have the disease, as recited in claims 23 and 31; see for example Link's figure 2, which clearly shows treating dendritic cells isolated from animals with EAE. However Link does not explicitly teach the administration of these cells to human patients.

It would have been obvious to one of ordinary skill in the art to modify the method of Huang to use autologous dendritic cells to treat human patients, as suggested by Link, with a reasonable expectation of success. The motivation to do so would be to reduce the possibility of immune rejection of transplanted cells. If the cells injected into the patient are autologous (i.e., from that patient), they will not be recognized as foreign and thus there will be no need for the use of immunosuppressant drugs. It would be reasonable to expect success when combining the teachings of the two references, as both are on point to treatment of autoimmune neurodegenerative diseases (MS and EAE) by administration of antigen-presenting cells that have been exposed to a particular set of biological molecules *in vitro*.

Double Patenting

11. Claims 23 – 28, 31 – 34, and 36 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 – 3, 6 – 28, 31 – 34, and 37 – 46 of U.S. Patent No. 6,267,955. Although the conflicting claims are not identical, they are not patentably distinct from each other because in each case the claims are drawn to methods of administering antigen-presenting cells that have been pulsed nervous-system specific antigens for treatment of diseases including those disease characterized by axonal damage.

Applicant traversed this rejection on the same grounds as the rejection under 35 USC 102 above, specifically on the grounds that the nerve segments are not antigens. As explained

in the rejection under 35 USC 102, nerve segments contain many NS-specific antigens and therefore the prior art claims anticipate the instant claims.

12. Claims 23 – 28, 31 – 34, and 36 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 – 26 of U.S. Patent No. 5,800,812. Although the conflicting claims are not identical, they are not patentably distinct from each other because in each case the claims are drawn to methods of administering antigen-presenting cells that have been pulsed nervous-system specific antigens for treatment of diseases including those disease characterized by axonal damage.

Applicant traversed this rejection on the same grounds as the rejection under 35 USC 102 above, specifically on the grounds that the nerve segments are not antigens. As explained in the rejection under 35 USC 102, nerve segments contain many NS-specific antigens and therefore the prior art claims anticipate the instant claims.

Inventorship

13. Claims 23 – 28, 31 – 34, and 36 are directed to an invention not patentably distinct from claims 1 – 3, 6 – 28, 31 – 34, and 37 – 46 of commonly assigned patent 6,267,955 and claims 1 – 26 of commonly assigned patent 5,800,812 as explained in the double-patenting rejections above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned 6,267,955 and 5,800,812, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

In the remarks filed 29 October 2007, applicant stated that a) there is no conflicting subject matter between the instant claims and those of the above-cited patents and b) the issue is moot as the patents are all owned by the same entity. The remarks are not sufficient to overcome the concerns as to who actually invented the subject matter now claimed. As concerns a), the reasons why the claims of the '955 and '812 patents anticipate the instant claims are set forth in the double-patenting rejections and the rejections under 35 USC 102. With respect to b), a statement that all patents are currently commonly owned is not sufficient to overcome the concerns. As set forth at p. 14 of the previous office action and p. 12 of this office action, to resolve this issue the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter. Neither criterion has been fulfilled, as the remarks only mention patents, not the subject matter of this application, and are silent as to whether the patents and the instant application were commonly owned at the time of invention of the current claims.

Conclusion

14. No claim is allowed.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel Kolker whose telephone number is (571) 272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Daniel E. Kolker, Ph.D.
January 17, 2008

ROBERT C. HAYES, PH.D.
PRIMARY EXAMINER